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STANDARD OPERATING PROCEDURE

Preparing and Approving Protocols, Reports, and Other Technical Documents

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KEY WORDS-
Formatting, executive summary, abstract, document review

APPROVALS

Original SOP signed by the following 10/12/99

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Environmental Hazards Assessment Program (EHAP) organization and personnel such as management, senior scientist, quality assurance officer, project leader, etc. are defined and discussed in SOP ADMN002.

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1.0 INTRODUCTION

1.1 Purpose

This Standard Operating Procedure (SOP) serves as a guide for writing protocols, reports, and other technical documents. Additional guidelines for writing these documents for studies conducted following Good Laboratory Practices (GLP) are also provided in this SOP. GLPs for protocols and final reports are listed in U.S. EPA 40 CFR Part 160.120 and 160.185, respectively. The approval process for these documents is also outlined in this SOP.

Projects conducted under grants, contracts, or other cooperative agreements may follow the format of the sponsor.

1.2 Definitions

1.2.1 A **protocol** is a written document detailing a study to be conducted. A protocol is prepared by the project leader with assistance from the senior scientist, statistician, or others closely involved with the study. Studies are conducted to (1) determine if a problem exists, or (2) address a problem. The protocol is written according to a standard format and must be approved through the review process prior to undertaking the study.

1.2.2 A **report** is prepared by the project leader, with input from the field coordinator, statistician, or others involved with the project. This document is written using a standard format and describes the results of a study. The report must be approved through the review process before the report is distributed outside the department.

1.2.3 A **technical document** may be a technical summary or memorandum which summarizes the results of a study, generally written prior to or in place of a report. These documents generally involve less time to draft and are a means of providing a brief, but broad idea of the study and its results.

1.2.4 Prior to final approval by the branch, protocols, in-house reports, and technical documents are routed through an **approval process** for a comprehensive review on subjects such as analytical method, chemistry, science, statistics, materials and methods, policy, and quality assurance and quality control.

2.0 ORGANIZATIONAL OVERVIEW OF THE PROTOCOL

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The following items are included as standard format in the design of a protocol.

2.1 *Header:* The header contains the name and address of the program and the date the protocol is approved. The header is typed, single spaced, with bolded text. The text on each line is centered between the left and right margins of the page.

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2.2 *Title*: The title should contain enough information to briefly describe the project. The title is typed, single spaced, using upper case letters, with bolded text. Text on each line is centered between the left and right margins of the page.

2.3 *Headings*: The following eight headings (introduction, objective, personnel, study plan, sampling methods, timetable, references, and budget) are components of the protocol. A protocol may include, but is not limited to these headings. Protocols conducted following GLP have additional headings. Each heading should be labeled in the protocol and proceeded by a Roman numeral (I through VIII).

The headings for non-GLP could include:

I. INTRODUCTION
II. OBJECTIVE
III. PERSONNEL
IV. STUDY PLAN
V. SAMPLING METHODS
VI. DATA ANALYSIS
VII. CHEMICAL ANALYTICAL METHODS
VIII. TIMETABLE
IIX. REFERENCES
IX. BUDGET

Protocols for studies conducted following GLP should have the following headings:

I. INTRODUCTION

2.3.1 through 2.3.15 describe GLP and non-GLP protocol headings.

2.3.1 *Introduction* (both)*:* The introduction provides a thorough explanation of the problem being addressed. Relevant background information, factual data, and assessment of the problem should substantiate: 1) what is the problem, 2) why is it a problem, and 3) where is the problem (if appropriate).

2.3.2 *Objective* (both)*:* The objective should be stated clearly and concisely, and identify the problem or hypothesis being addressed in the protocol.

2.3.3 *Personnel* (both)*:* This section provides information on personnel involved in the study. If staff from other state, federal, county agencies or private organizations are involved in the project, they should be included here, unless the study is GLP. If the study is conducted following GLP, staff from other agencies or organizations should be listed under Collaborators.

The personnel section should be presented as outlined, below.

> This project will be conducted by the Environmental Hazards Assessment Program, under the overall supervision of... (insert name of project supervisor here). Other key personnel include:
>
> Project Leader - Name
> Field Coordinator - Name
> Statistician - Name
> Quality Assurance/Laboratory Liaison - Name

Chemist - Name
Senior Staff Scientist - Name
Agency and Public Contact - Name

Responsibilities of key personnel are described in EHAP Standard Operating procedure ADMIN002.00. Authorship of the final report may include but not limited to the personnel named above.

It should be stated that questions regarding this study be directed to the Agency and Public Contact person(s). A phone number and an e-mail address should be included.

2.3.4 *Testing Facility and Personnel* (GLP): The Testing Facility and Personnel section should list all testing facility addresses such as the main office, warehouse, laboratory and any satellite offices to be used. The personnel part of this section follows the same procedure as in 2.3.3 above.

2.3.5 *Study Plan* (both): If applicable, the study plan should explain the formal study design and the appropriate methods that will be used to ensure that the objective is clearly measurable. This includes defining the area of the study plot, the number of sites used in the project, the media to be sampled, the number of treatments and replications, the sampling time intervals, the number of samples collected, and so forth. Include other parameters to be measured in the study such as weather, water flow, water depth, pesticide deposition, treatment dates, and so forth. Tables and figures may be included in the protocol to aid the reader in understanding the project.

2.3.6 *Sampling Methods* (both): The sampling methods section should provide a detailed, sequential list of the activities that will be followed in the study. Identify the procedures for collecting data including how the samples will be collected, how they will be stored, equipment that will be used, and so forth. This section includes a list of pesticides (test substances) to be analyzed and analytical methods to be used, sample storage and transport procedures, quality assurance and quality control measures. Relevant SOPs and analytical SOPs (methods) should be cited. For GLP studies, these SOPs should be attached to the protocol.

2.3.7 *Timetable* (both)*:* The time schedule should be reasonable and give an estimated date (approximate month and year) for field monitoring, chemical analysis, data analysis, report preparation, and any other parameters not mentioned, but pertinent to the preparation and completion of the study. GLP protocols should

include both experimental start and termination dates.

2.3.8 *Sponsor* (GLP): The name of the contact person from the agency sponsoring the study along with the agency name and address.

2.3.9 *Collaborators* (GLP)*:* List name(s) of collaborator(s), their agency/organization(s) and address.

2.3.10 *Test Substance (GLP):* List the chemical name(s) of the pesticide(s) to be monitored or examined in the study.

2.3.11 *Selection of the test system (GLP):* List matrix(es) to be collected and sites to be examined as well as the justification for the selection of both*.*

2.3.12 *Data Analysis (both):* The proposed methods of statistical analysis to be used for each type of data collected (e.g. regression or ANOVA) in this section.

2.3.13 *Records to be maintained (GLP): Lists which records will be maintained and where. Generally the SOP ADMIN005 for Archiving can be sited in this section.*

2.3.14 *References* (both)*:* If references are cited, they should be listed on a separate page using the reference, Publication Handbook & Style Manual, 1998. Include the full journal title.

2.3.15 *Budget (non-GLP):* The budget estimates the cost of the study from the time of initiation to the time of completion. The budget should include itemized expenses for personnel; and operating expenses: equipment and supplies, travel, laboratory costs, contractual work and any other anticipated expenditures. List each item and the approximate cost. Subtotal the dollar amounts for personnel cost and operating expenses, and include a grand total amount for the study. The budget should be listed on a separate page.

2.4 After the protocol is written; follow the approval procedure outlined in section 5.0 below.

3.0 ORGANIZATIONAL OVERVIEW OF THE REPORT

The report should contain relevant information with enough details, so that if necessary, the project could be duplicated by anyone without having to seek additional information.

The report contains distinctive component parts such as the title, executive summary,

abstract, introduction, materials and methods, results, discussion, conclusions, references, and appendices, but sometimes it may be desirable to organize the headings differently so that two sections are combined - such as results and discussion versus an individual heading for each subject. Nonetheless, the essential components of a report are discussed below.

3.1 *Title*: The meaning of the title and order of words are important and should highlight the significant contents of the paper. It should not contain chemical formulas or proprietary names. The title is single spaced using upper case letters, with bolded text. Text on each line is centered between the left and right margins of the page and generally should not exceed 10 to12 words.

3.2 *Authorship*: The listing of authors should include those persons who substantially and actively participated or contributed to the design and execution of the study. Authors should include, but are not limited to the project leader, the field coordinator. The names of those involved with the study will appear on the cover page of the report.

Other personnel who contributed to the study should also be acknowledged either on the inside title page or in the Acknowledgment section of the report. Recognition should be given to those who participated in the subjects listed below or to staff in a program (e.g., EHAP) in general.

Field Monitoring and Sampling
Study Design and Statistical Analysis
Method Development and Chemical Analysis
Soil Composition and Water Quality Analysis
Quality Assurance and Quality Control
Modeling
Executive Summary
Graphics

3.2. *Executive Summary*: The project supervisor will consult with management to determine if an executive summary is needed. If needed, the Branch Chief and Public Contact person will draft the executive summary after the report is written and have it reviewed by the project leader, the project supervisor and the communication officer. The executive summary gives a synopsis of the report in layperson terms and puts the results into context. The executive summary compares the residue concentrations detected with health or environmental standards or guidance levels. Possible regulatory action or other mitigation measures may be discussed.

3.3 *Headings*: The following eight headings (abstract, introduction, materials and methods, results, discussion, conclusions, references, and appendices) are common

components of the in-house report. A report may include, but is not limited to these headings.

3.3.1 *Abstract*: The abstract should contain a concise statement of the scope of the project, the objective, the methodology, results, and include the main conclusions. It is a summary of the information in the report and should not exceed 250 words. Do not include references, tables or figures in the abstract.

3.3.2 *Introduction*: The introduction should contain relevant background information with regards to the project. It should contain enough information so the reader can follow the discussion and interpret the results without needing to refer to previously written articles on the subject. The last segment of the introduction should describe the need for the project and the objective as listed in the approved protocol.

3.3.3 *Materials and Methods*: The materials and methods section contains information needed to repeat the testing procedures used in the project. It describes why and how you obtained the results. The information included in the materials and methods section should be similar to the information presented in Study Plan and Sampling Methods sections of the protocol (2.3.4 and 2.3.5). Include the technical specifications of equipment used (instrument names and model number) and stability of pesticides (test substances), if applicable. The quality control procedures should also be included in this section, as well as statistical procedures if not under their own heading. A description of the transformations, calculations or operations performed on the data should be included in a GLP study final report. Any relevant SOPs pertaining to methods and sample collection used in the study should be referenced, and for a GLP study, must be placed in the appendices of the report.

3.3.4 *Results*: The results section should briefly describe the overall study without repeating the experimental procedures in detail. The findings that you observed in the study should be clearly stated in the text, tables and figures. Tables and figures should be able to stand alone (i.e., presented in a meaningful way, such that the reader can simply look at a table and understand what data were collected). Report here if results are adjusted, e.g., for analytical method recovery, and include data used to justify the adjustment. Detailed data may be listed in the appendix.

3.3.5 *Discussion*: The discussion section is designed to tell what the results mean. The data should support the principles, relationships, and generalizations stated in the discussion. Show how your results and interpretations

are either similar or dissimilar to previously published work. The results and discussion sections may be combined instead of having two separate headings. A description of all circumstances that may have affected the quality or integrity of the data should be included in the report and may be presented in this section. The discussion section is the place where new ideas and speculations may be presented as long as there is data to support them.

3.3.6 *Conclusions*: The conclusions should be summarized and stated clearly and succinctly. Emphasize the main points brought out in the discussion. There should be no new information presented.

3.3.7 *References*: If references are cited, they should be listed on a separate page using the reference, Publication Handbook & Style Manual, 1998, American Society of Agronomy.

3.3.8 *Appendices*: Appendices carry supplemental material such as illustrations and tables which elaborate or support the text, but because the appendices are placed in the back of the report, they do not distract the reader from the text=s main ideas. Examples of other materials placed in the appendices include such things as raw data, quality control data, SOPs, statistical procedures, and so forth.

If two or more appendixes are placed in a report, they are either numbered with roman numerals, or lettered consecutively.

3.4 Additional GLP headings or items

There are additional headings or items not included above that should be included in a GLP study report. The order of these headings and the above headings could follow the order listed for the GLP protocol in 2.3.

3.4.1 *Testing facilities and personnel*: The testing facilities (name and address) and personnel involved in the study such as the name of the project leader (study director), the names of other scientists or professionals and the names of all supervisory personnel involved in the study must be listed in the final report. May be organized as in 2.3.3 and 2.3.4.

3.4.2 *Archiving:* The location where all specimens, raw data and the final report are to be stored needs to be noted in the report. Noting that SOP ADMIN005 will be followed for archiving would be adequate.

3.5 After the final report is written, follow the approval procedure outlined in Section 5.0 below.

4.0 ORGANIZATIONAL OVERVIEW OF THE TECHNICAL DOCUMENT OR MEMORANDUM

The technical document such as a technical summary or memorandum may contain the component parts such as a summary, introduction, materials and methods, results, and references. The discussion and conclusion segments may be included in the technical document, although it is typical to omit them since greater detail will be given in the report. A technical document or memorandum is not an acceptable final document for a GLP study since a final report must be written for all GLP studies.

A technical summary or memorandum may include the following:

4.1 *Summary*: The summary should provide a brief overview of the study and the results. The technical summary may only be a one page summary of the study.

4.2 *Headings*: Most EHAP study memorandums have headings. Technical summaries may have headings. Each heading should be labeled in the document. Generally the headings are as follows:

INTRODUCTION
MATERIALS AND METHODS
RESULTS
REFERENCES

4.2.1 *Introduction*: See 3.2.3. As and alternative to the introduction, two sections titled Scope of this Memorandum and Background may be used.

4.2.2 *Materials and Methods*: Follow 2.3.5, 2.3.6 and 3.3.3. SOPs for procedures and methods should be referenced, but do not need to be included with the document.

4.2.3 *Results*: The results section clearly states the findings that you observed in the study. There should be clear presentation of the text, tables, and figures.

4.2.4 *References*: If references are cited, they should be listed on a separate page using the format in Publication Handbook & Style Manual, 1998.

4.3 After the technical document or memorandum is written, follow the approval procedure outlined in Section 5.0, below.

5.0 APPROVING PROTOCOLS, REPORTS, AND OTHER TECHNICAL DOCUMENTS

Protocols, reports, and technical documents must be submitted through an approval process for a comprehensive review on subjects such as science, materials and methods, analytical method, chemistry, quality assurance and control, statistics, policy, editorial accuracy, and additional categories when considered appropriate. Attachment A is the Author=s Checklist for EH-Report Publication. The checklist may be helpful to the author during the review process and during publication.

5.1 Internal Document Review

The EHAP Document Review Form (Attachment B) is a routing slip attached to a copy of a completed protocol, report, or technical document. This form is completed by the project supervisor and, with the attached manuscript, is routed to each of the appropriate reviewers (co-authors and cooperators of the study) for his/her comments on specific categories checked-marked on the review sheet (i.e. science or materials and methods). The reviewer is given a specific time period in which to review the document and will either accept the document with no or minor changes or suggest major revisions, which will be listed on the review form for the project leader to address. The reviewer will also indicate on the review form whether to request a review of the next draft of the document after changes are made or if no further review of the document is necessary, then the reviewer will sign his/her name on the approval line indicating that the categories reviewed were acceptable. All documents must be approved in each reviewed category before further action is taken. For GLP studies a copy of these review sheets must be included in the appendix.

When needed, the program supervisor will then have the public contact person write an executive summary for the branch chief=s approval (see 3.2). Then the program supervisor will submit the protocol, report, or technical document together with the executive summary for management review. A standard route slip will be attached and briefly describe the documents. The documents will follow the normal chain-of-command (program supervisor, branch chief, assistant director, and so forth). At each step, the management reviewer will have the option of returning the document for revision, passing

the documents to the next level or giving final approval.

5.2 External Document Review: The program supervisor will also consult with management to decide which, if any, outside entities (e.g., other agencies, universities, stakeholders) should review the protocol, report or technical document. Management will also decide if the outside review should occur before, concurrently, or after management review. Outside review will be coordinated by the project supervisor and/or Agency and Public contact person. The Agency and Public contact person will compose a cover letter to accompany the document. The cover letter will briefly describe the document and give a deadline for comments.

5.3 GLP Study approval

In addition to approval outlined in 5.1 and 5.2, GLP studies are required to have proper signatures and approval listed below.

5.3.1 GLP protocols must include the date of approval of the protocol by the sponsor and the dated signature of the study director prior to conducting the study. All changes in or revisions of an approved protocol and the reasons must be documented, signed by the project leader, dated and maintained with the original protocol.

5.3.2 A statement prepared and signed by the Quality Assurance Unit must be included in the final report that specifies dates inspections were made and findings reported to management and to the project director.

5.3.3 The final report must be signed and dated by the project director.

5.3.4 Corrections or additions to a signed final report shall be in the form of an amendment by the project director. A copy of the final report and of any amendment shall be maintained by the sponsor and by the test facility.

6.0 PROCEDURE AFTER OBTAINING ALL NECESSARY APPROVALS

After final approval, the project leader and contact person are responsible for reproducing and disseminating the document to all cooperators and interested parties. A mailing list should be stored in the study archives.